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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/956,991	10/23/97	KORENBERG J	P-CE-2817

EXAMINER	
TUNG, M	
ART UNIT	PAPER NUMBER
1644	25

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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PTO-90C (Rev 11/00)

Advisory Action

Application No.	Applicant(s)
08/956,991	Korenberg
Examiner	**Group Art Unit**
Mary B. Tung	1644

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☒ Appellant's Brief is due two months from the date of the Notice of Appeal filed on Nov 8, 2000 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Nov 8, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☐ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s): _____

_____ would be allowable if submitted in a

☐ Newly proposed or amended claims _____ separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

See attached

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: 44-46

Claims objected to: _____

Claims rejected: 1, 31-43, and 47-49

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Other

David B. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 / 644

Serial No. 08/956,991
Art Unit 1644

SUPPLEMENT TO ADVISORY ACTION

Claims 1-30 were originally elected.

Claims 2-10, 12, 20 and 30 were cancelled in the paper filed 2/16/00, Paper No. 17.

Claims 31-49 were added in Paper No. 17.

Claims 11, 13-19 and 21-29 stand withdrawn as being drawn to a non-elected invention.

Claims 1 and 31-49 are under consideration.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Applicant's arguments filed in Paper No. 17 have been fully considered but they are not persuasive.

3. Claim 1, **34, 35, 38 and 41** stand rejected under 35 U.S.C. 102(a) as being anticipated by Korenberg, et al. *(PNAS USA, 91;4997-5001, 1994)*, for the same reasons set forth in the action mailed 8/16/99, Paper No. 15.

4. Korenberg, et al. teach an isolated nucleic acid obtained from patients with Down Syndrome (see the abstract and page 4997, col. 1, last paragraph and bridging over to page 4998, col. 1). DS-CAM would inherently be encoded by nucleic acid taught by Korenberg, et al, absent evidence to the contrary. The isolated chromosomal DNA isolated for Southern blot analysis, as taught on page 4998 would also be expected to hybridize to SEQ ID NO: 1 under the recited conditions, absent evidence to the contrary. Claims 33 and 35 are included because of the high homology among the sequences identified as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.

5. The Applicants argue that Korenberg, et al. do not teach the claimed invention because "none of the claimed nucleic acid molecules were isolated or purified away from the

rest of the genes in the genomic DNA sample." [underlining added by Applicants] This argument is not found persuasive, however, because the isolation necessary for gel electrophoresis is encompassed by the claimed invention. It is suggested that the Applicants insert the wording similar to claim 31, which recites an intronless sequence in order to overcome this rejection.

6. Claims 33-37, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Genexpress cDNA Program *(GenBank, Accession # F13426)*.

7. The F13426 sequence listing teaches a 309 bp fragment of nucleic acid which encodes a 103 amino acid fragment of SEQ ID NO: 2. The F13426 sequence listing teaches that the sequence fragment has a 95.1% identity with the nucleic acid sequence that encodes SEQ ID NO:2. The F13426 sequence listing also teaches the cDNA, as recited in claim 47 was cloned into a ***lafmid BA*** vector and a mRNA sequence, as recited in claim 48. Claims 36 and 37 are included because the ***lafmid BA*** vector was derived from the pEMBL vector, which is an *E. coli* to yeast shuttle plasmid vector and thus requires a host (recombinant) cell for storage and shipment as evidenced by ATCC Catalog No. 37395. Claims 33 and 35 are included because of the high homology among the sequences identified as SEQ ID NOS: 1, 7, 8, 9 and 10, which encodes SEQ ID NO: 11, as recited in claim 33, one would expect hybridization of said sequences under the claimed conditions, absent evidence to the contrary.

8. The Applicants argue that the nucleic acid sequence of F13426 are merely similar to SEQ ID NO: 1 and does not hybridize to any portion of the nucleic acid encoding SEQ ID NO: 11 and therefore does not anticipate the claims. However, F13426 is similar to SEQ ID NO: 10, which encodes SEQ ID NO: 11, between residues 5115-5398, with a 95.4% homology and thus would hybridize to the claimed sequence.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10. Claims 1, 31-43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korenberg, et al. ***(PNAS USA, 91;4997-5001, 1994)***, in view of Gallatin, et al., (US Patent No. 5,525,487).

11. Korenberg has been discussed, *supra*. Korenberg does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, host cells transfected with a vector comprising a nucleic acid, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by Korenberg in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The Applicants argue that Korenberg does not teach the claimed invention, and thus there is no suggestion or motivation to combine Korenberg with Gallatin. The arguments concerning Korenberg are discussed, *supra*.

13. Claims 33-37 and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genexpress cDNA Program ***(GenBank, Accession # F13426)***, in view of Gallatin, et al., (US Patent No. 5,525,487).

14. # F13426 has been discussed, *supra*. # F13426 does not teach or a method for expression of a DS-CAM related protein. However, the '487 patent teaches that in order to produce the polypeptide in large quantities, the host cells, can be used in a method of expressing the polypeptide then isolating the polypeptide from the cell culture medium, as recited in claim 49, (see col. 3, lines 12-17). One of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA taught by # F13426 in a method for expression of a DS-CAM related protein, in order to produce large quantities of the protein as taught in col. 3. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The Applicants argue that F13426 does not teach that the nucleic acid is located on chromosome 21 or that it encodes an adhesion molecules. However, this argument is not found persuasive because the location on the chromosome or the function of the encoded sequence is an adhesion molecule are inherent properties of the nucleic acid and lend no patentable weight to the claimed invention. Additionally, the Applicants argue that there is no motivation to combine with Gallatin. This is not found persuasive, however, because Gallatin provides motivation, in that it is a general teaching as to what is well-known in the art at the time the invention was made, and therefore, one of ordinary skill in the art would have been motivated to combine Gallatin with GenBank Accession No. F13426 in order to produce large quantities of the protein as taught in col. 3 of Gallatin.

Allowable Subject Matter

16. Claims 44-46 are allowed. The prior art does not teach a nucleic acid sequence set forth in SEQ ID NOS: 5-8 or 10, which encodes SEQ ID NO: 11, 15 nucleotides or longer.

Conclusion

17. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

April 10, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640